

Product Designs Which Encourage -- Or Discourage --  
Related Innovation by Users: An Analysis of Innovation  
in Automated Clinical Chemistry Analyzers

by

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## ABSTRACT

In this paper we examine the level of user innovation activity related to different brands of the same type of product - automated clinical chemistry analyzers. Strong interbrand differences are found in user involvement in such innovation tasks as the development of new chemical test methods for use on the different analyzers studied. We test the speculation of interviewees that the cause of the differences observed lies in details of the design of the analyzers studied which makes some easier for users to modify than others, and find it supported by our data. As product design is a variable under the control of product manufacturing firms, this finding suggests that manufacturers can, in at least some product categories, influence the level of user innovation related to their products via product designs which encourage or discourage such activity. Related costs and benefits are discussed.

## 1.0 Introduction

Students of the technological innovation process have long sought characteristics of firms, industries, technologies, regulatory environments, etc. which correlate with and might contribute to successful innovative activity. Over the past few years, one of the variables studied to this end has been the role of the user in the industrial product innovation process. To date, it has been shown that in some industries, users play a major role in that process - actually developing 60-80% of the innovative products sampled<sup>(1,2)</sup> - while in other industries, the user appears to play a minor role, with most products sampled being developed by the product manufacturer.<sup>(3,4)</sup> In still other industries, the proportion of product innovations developed by users has been seen to diminish relative to that of product manufacturers with the passage of time.<sup>(5)</sup>

All of the above-cited studies provide data on the innovation role of the user at a fairly high level of aggregation ("industry",<sup>(6)</sup> "technical area"<sup>(9)</sup>). Logically, therefore, speculation as to the causes of the patterns seen has also tended to revolve around industry-level variables. It is important to keep in mind, however, that variables operating at the level of the individual firm and even the individual product may also have an important impact on the role of users in the innovation process. In this paper, we will test the proposition that the innovation role of the user can be seen to differ significantly between products which are functionally very similar. We will then go on to suggest that a variable operating at the level of the individual product - product design - may play a role in creating the differences observed.

## 2.0 Type of Product to be Examined

The type of product which we have selected for study is the automated clinical chemistry analyzer. Our decision to explore this product type was not derived from theoretical insight. Rather, two eminently practical considerations

were determining:

- 1) One of the authors (S.F.) is a physician specializing in clinical chemistry.
- 2) A great deal of product innovation has taken place in the category in the last 20 years.

Readers unfamiliar with automated clinical chemistry analyzers and their uses may find some contextual information helpful. Automated clinical chemistry analyzers are used in clinical laboratories - a large and growing industry. (According to Smithson,<sup>(8)</sup> there were approximately 14,000 clinical laboratories in the U.S. in 1975. Some 50% of these were affiliated with hospitals, 30% were affiliated with M.D. offices, and 20% were independent commercial entities. Their aggregate revenues were on the order of \$6.2 billion in 1975 and growing at 10% annually.) The role of clinical laboratories is to perform tests on samples of human body fluids and tissues at the order of physicians or other health care practitioners. Test results are reported back to these practitioners for use in the diagnosis and management of their patients.

Tests performed by clinical laboratories are traditionally divided into the four major categories of clinical chemistry, hematology, bacteriology, and serology. Those in the clinical chemistry category - the one we will examine - are used to determine the level of a chemical, such as glucose, in a patient's blood. Typically there are several "methods" available by which a particular "test" (such as blood glucose) can be performed. The execution of a clinical chemistry test method involves combining a sample of a patient's serum with one or more reagents and then allowing the chemical reaction(s) thus initiated to take place under prescribed conditions of time, temperature, etc. Substances which would interfere with the test measurement are removed (by precipitation, dialysis, or other means), the test measurement is made (via techniques such as colorimetry, fluourometry, etc.) and the test result recorded.

Since the 1950's, automated clinical chemistry analyzer equipment has been available which, as the name implies, can carry out clinical chemistry tests automatically. Such equipment has been widely adopted despite prices on the order of \$20-200 thousand dollars per unit (Reportedly<sup>(9)</sup> 44% of the 677mm clinical chemistry tests performed in hospital labs in the U.S. in 1977 were performed on automated clinical chemistry analyzers). Automated clinical chemistry analyzers are said to be cost-effective because they reduce the labor content per test from the 50% which was the rule of thumb for manual methods to about 5%, while at the same time reducing the incidence of test errors.

### 3.0 Speculations Regarding Analyzer- Based Test Development by Users

Manufacturers of automated clinical chemistry analyzers usually also specify procedures and sell materials (pre-mixed reagents, etc.) which can be used together with their equipment to perform certain frequently-requested clinical chemistry tests. Analyzer users who wish to perform a commercially-available test by a method different than that offered by the manufacturer - or who wish to perform a test not commercially available - must develop an analyzer-compatible method on their own or find an appropriate method reported in the research literature.

It seemed to us that manufacturers of automated clinical chemistry analyzers should find such user method development activity involving their equipment of potential interest because:

- the value of a clinical chemistry analyzer is, obviously, a function of the tests it can perform
- test methods developed for use on one type of analyzer usually cannot be transferred to another type without adaptation work - and sometimes cannot be transferred at all because of differences in equipment

operating characteristics.

We therefore decided to explore our speculation that different types of functionally similar products (here, different types of automated clinical chemistry analyzer) could show significant differences in the innovation role of the user by exploring extant user test development activity involving different types of automated clinical chemistry analyzer.

Our examination of this issue was begun by contacting several professionals in clinical chemistry labs who had recently published research involving the use of automated clinical chemistry analyzers. We asked these analyzer users whether any of the three brands of automated analyzers<sup>\*</sup> most commonly available in hospital clinical chemistry labs in 1977 (Technicon, DuPont, and Abbott<sup>\*\*</sup>) were more likely to be used in the development of new clinical chemical test methods by users than others. All contactees felt that Technicon and Abbott Labs equipment was quite likely to be used for this purpose but DuPont equipment was not likely to be - and that the reason involved a particular aspect of the design of the analyzers manufactured by these companies. More specifically, they suggested that the design of the "reagent system" portion of the DuPont autoanalyzer equipment presents a major barrier to any non-DuPont personnel who might wish to develop chemical test methods for use on it, and that such a barrier does not

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\* A generally accepted definition for what constitutes "automated" equipment for the performance of such tests does not exist. IMS (cf.\*\* below) solves the problem in its surveys by asking respondents to indicate whether "automated chemistry analyzers, such as AutoAnalyzer or Robot Chemist [were used]." AutoAnalyzer and Robot Chemist are the brand names of equipment which, when given a blood serum sample as an input, will perform all the steps required to execute a chemical test automatically and present a test result to the technician on a meter or printout as output. The equipment we will study fits these performance criteria.

\*\* Source of data is IMS<sup>(9)</sup>. IMS generates its data by surveying and auditing lab records of 204 of the approximately 5,800 non-federal, short term hospitals in the U.S. The sample of hospital labs used is stratified by bed size, region, and hospital ownership. IMS restricts circulation of its data; it is used here by permission of the company.

exist on the Technicon and Abbott Labs equipment.\* Telephone interviews with product managers in the Technicon, DuPont and Abbott Labs automated analyzer groups yielded a similar assessment and interpretation.

When we studied the design of analyzers built by these three manufacturers, the interviewees opinion on this issue seemed to us to pass a "test of reason" with ease. So that our readers may have an opportunity to make this judgement for themselves, we provide capsule descriptions of the portions of the DuPont, Technicon and Abbott Labs automated analyzer systems which are relevant to the issue.

- DuPont automated clinical chemistry analyzer systems can be seen as made up of two major components, the analyzer equipment itself and single use, disposable, factory sealed "test packs" supplied by DuPont. DuPont currently offers owners of its analyzer equipment factory-supplied methods for thirty six tests, each requiring a test pack tailored for that test method only. The test packs are complex and carefully designed to be "fool-proof" - e.g., usable even by minimally trained operators. They consist, in essence, of plastic pouches divided internally into several sealed compartments which contain reagent quantities needed for a single execution of a particular test. The pouches, in turn, are sealed to a plastic "header" which contains a serum inlet valve and, for tests which require it, a built in chromatographic column for one-time use which removes substances which would interfere with the needed test measurement. All chemical reactions required for a test occur inside the disposable test pack - the pack itself is never opened during its transit through the analyzer equipment. Even the results of the test are determined without opening the pack, by passing

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\* Technicon offers several models of automated clinical chemistry analyzer, Abbott Labs offers two models and DuPont one. All models of a given manufacturer are fitted with the same type of reagent proportioning system, however. As a consequence, we will be able to examine the interviewees' hypothesis by collecting data on analyzer brands rather than on specific models of analyzer.

a light beam through its transparent walls.

- Technicon automated clinical chemistry analyzer models are based on a principle called "continuous flow analysis", and function much like miniature, continuous-process chemical plants. Technicon's product design philosophy over the years has been to build a series of functional modules - e.g. pump modules, dialyzer modules, etc. - which may be used as system building blocks. Systems capable of performing a particular chemical test are assembled by selecting certain of the available modules and interconnecting them into appropriate hydraulic circuits by means of small-diameter plastic tubing. Tests are then run by supplying reagent, patient serum samples and compressed air (used to create bubbles of air in the tubing which isolate one patient's test material from another's) to appropriate points in the hydraulic circuits. Pump modules in the system combine these in the proper proportion and sequence and move them through the system to accomplish the test.

Technicon offers its customers standardized assemblies of modules and tubing for the performance of the test methods it makes available commercially. Modules and tubing may also be purchased separately, however, and experimenters who wish to may quickly and conveniently assemble these into unique configurations which will allow them to perform test methods not offered commercially.

- Abbott Labs automated clinical chemistry analyzers meter the amount of reagent(s) needed for a particular test from bulk reservoirs into transparent, disposable, open-topped plastic cups called "cuvettes". Samples of patient serum are also metered into these cuvettes and the desired reaction is allowed to proceed at a specified temperature and for a specified time. When the required time has elapsed, individual test results are "read" by passing a beam of light through the transparent walls of individual cuvettes. Users may either fill the reagent



reservoirs with Abbott-specified materials or with materials of their own design.

On the basis of the above capsule descriptions of portions of the DuPont, Technicon and Abbott Labs automated analyzer systems, the reader may now be in a position to appreciate why users would find it easier to develop and execute test methods not available commercially by using Technicon or Abbott Labs equipment than by using DuPont equipment. Technicon modules may be purchased and connected up in a novel configuration. In both Technicon and Abbott equipment, desired novel reagents can be mixed up in bulk, placed in the machine's reservoirs, and the machine will meter out the proper amount of reagent(s) and serum needed for each test. Setting up the same novel method on DuPont equipment, on the other hand, starts with buying empty test packs from DuPont (empty packs without chromatographic columns are for sale: They have a standard use in machine calibration). Given that the test can be done by using the size and number of reagent compartments available in the empty pack, the experimenter must next inject precisely measured amounts of reagent into selected compartments of each pack and then reseal the compartments. If 1,000 tests are required for an experiment, he must perform these operations on 1,000 packs. This would clearly be a great effort - and the end result would be the accomplishment of a reagent porportioning task which Technicon and Abbott Labs equipment does automatically.

#### 4.0 Test of the Speculation

In the preceeding section, we discussed the speculation of interviewees that Technicon and Abbott Labs automated clinical chemistry analyzers were more likely to be chosen by users for research involving the development of new clinical chemistry test methods than were DuPont analyzers. We should now note that development of novel test methods is not the only kind of clinical chemistry

research engaged in by users: They also conduct research involving test methods commercially supplied by analyzer manufacturers when such are appropriate. (e.g.: "The blood glucose level of 300 type Y patients was determined via the \_\_\_\_ method sold by DuPont for use on its automated clinical analyzer equipment and it was found that ...".) The existence of these two types of research by users of automated clinical chemistry analyzers - (1) research involving test methods made commercially available by equipment manufacturers and (2) research involving test methods developed by users themselves - suggests a way by which we can test the speculation of the interviewees. If DuPont automated clinical chemistry analyzers are less appropriate for research involving user developed test methods than are the Technicon and Abbott Labs analyzers, then this should be visible in the research literature: That is, the ratio of research reports involving commercial vs. user-developed test methods should be significantly higher when DuPont analyzers are used in the research than when Technicon or Abbott Labs analyzers are used.

We decided to test the above hypothesis by means of MEDLINE, a computerized index of the medical literature made available by the National Library of Medicine, Bethesda, MD. The MEDLINE system provides access to articles published in most biomedical journals (approximately 3,000) from 1964-1975 to the present via title, author, "subject heading" and "textword". ("Subject headings" are assigned to articles by indexers working for the National Library of Medicine as a function of the subject matter dealt with in the article. A thesaurus of standard subject headings is maintained for use by indexers and those wishing to retrieve citations by use of these. "Textwords" are simply any word or combination of words. Users of the system may specify textwords and the system will flag articles containing them in the article title and/or abstract. Abstracts of most articles are contained in the MEDLINE data base from 1975 to present.)

We began our test by determining from the MEDLINE thesaurus<sup>(10)</sup> that "autoanalysis" was the subject heading assigned to papers involving the use of clinical chemistry autoanalyzers. Next, we decided to search the data base from the period January 1975 - the date article abstracts were first incorporated - to January 1978. (The search was performed in April, 1978, and at that time the most recent articles in the data base were published in January, 1978.) The system was instructed to identify articles which indexers at the National Library of Medicine had coded under the subject heading "autoanalysis", which also contained the names of DuPont, Technicon or Abbott Labs as "textwords" in the articles' title and/or abstract. Copies of the papers thus identified were obtained and examined by the authors. Those found to report research involving use of automated clinical chemistry test equipment manufactured by the named firms were coded according to the content categories of table 1 and the resulting citation counts entered into the data columns of the table.

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Insert Table 1 Here

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Note that this citation-search procedure does not identify all research publications involving autoanalyzer equipment. Rather, only that - possibly small - subset which names the equipment manufacturer in title and/or abstract is identified. Total citations found for each instrument brand is an indicator of the relative frequency of brand usage for research purposes if we assume that authors have no significant interbrand bias regarding explicit identification of the manufacturer of equipment used in title and/or abstract. The test we wish to make, however, - relative frequency of two categories of research usage for each of three brands of analyzer - is independent of such an assumption .

As will be seen from table 1, the results of our test support the

Table 1: Frequency of User Research Articles Involving Commercially Supplied vs. User-Developed Chemical Methods as a Function of Manufacturer of Analyzer Used

Number of Articles Found Reporting

Research by User Personnel

Only<sup>(a)</sup> which Involved:

Manufacturer- "Commercialized" <sup>(b)</sup> Chemistries	Researcher- Developed Chemistries	Was performed on Automated Clinical Chemistry Analyzers Manufactured by:
20	22	Technicon
6	0	DuPont
5	6	Abbott Labs

(DuPont vs. Technicon  $p = .02$   
DuPont vs. Abbott Labs  $P = .04$   
Fisher exact)

Notes: (a) Since our goal is to determine user ability to and interest in modifying manufacturer-supplied chemistries for the analyzer brands listed above, papers written by manufacturer personnel only or written jointly by manufacturer and user personnel are excluded. (One paper thus excluded was written jointly by a DuPont and user research team and reported a researcher-developed chemistry for the aca (11). Via telephone inquiry we determined that the test packs used in the research were filled to the researchers specifications at the DuPont plant. This would be in line with the interviewees hypothesis that users would find it hard to do this task themselves).

(b) DuPont commercial chemistries are always sold to the user prepackaged (see text). Technicon "commercialized" chemistries may be either pre-mixed reagents sold to the user or Technicon-specified formulas which the user mixes up in his laboratory as needed.

speculation of interviewees regarding the pattern of research usage of Technicon, DuPont and Abbott Lab's automated clinical chemistry analyzers. For our sample of articles, we find  $p = .02$  that users are as likely to conduct research involving non-commercial vs. commercial chemistries on DuPont vs. Technicon analyzers and  $p = .04$  that users are as likely to conduct research involving non-commercial vs. commercial chemistries on DuPont vs. Abbott Labs equipment (Fisher exact).

#### 5.0 An Alternate Explanation

While the test just described was targeted very specifically towards the speculation of interviewees that the DuPont automated clinical chemistry analyzer was less appropriate than Technicon and Abbott Labs analyzers for user development and implementation of test methods due to the design of its reagent system, alternate explanations for our table 1 data may be suggested. We will therefore briefly address one such which has occurred to us - others may occur to the reader - as follows: As we mentioned in the introduction, it has been shown that, in some instances, user innovation activity appears to diminish over time.<sup>(5)</sup> Is it possible that this effect could explain our data? Obviously, we have controlled for any time-effect impacting the whole automated clinical chemistry analyzer category by measuring user innovation activity during the same, 1975-78 time period for all analyzers examined. But what if researcher interest in a particular analyzer brand characteristically changes with the passage of years since that brand's commercial introduction (perhaps typically diminishing over the years as the equipment becomes obsolete - or perhaps typically rising over the years as researchers become more cognizant of the equipment's research potential). Since the first Technicon analyzer was commercially introduced in 1955, the DuPont analyzer in 1970 and Both Abbott Labs analyzer models (the ABA-100 and the ABA-50) in 1972, the pattern of user method development levels which we

have observed (Technicon and Abbott Labs high, DuPont low) does not appear consistent with this type of explanation.

## 6.0 Potential Value of User Method

### Development Activity to Analyzer

#### Manufacturers

In the previous section we have found support for the notion that aspects of the design of functionally very similar products (automated clinical chemistry analyzers) can have a major impact on the level of user innovation activity related to those products (development of test methods for use on analyzer equipment). To some extent, the interest of this finding for innovation researchers and practitioners depends on whether some of the user innovation activity observed is directed toward development of methods of potential value to many users. The methods of interest to the most users - and thus of greatest commercial interest to analyzer manufacturers - are, of course, those methods most frequently used by clinical chemistry laboratories. It therefore seemed to us that one might make an initial assessment of the issue noted above by determining whether user innovation activity can be seen in the development of the "analyzer compatible" versions of a sample of commonly used test methods currently sold commercially by analyzer manufacturers.

Because of the complexity of the data collection task to be described below, we decided to restrict our investigation to the most commonly-used test methods offered by Technicon and DuPont only for use with their analyzer equipment. Our sample of such methods was selected in a straightforward manner: a list of the 20 most frequently performed clinical chemistry tests was obtained.<sup>(9)</sup> Automated methods for performing 20 of these tests are offered by Technicon and 18 by DuPont, which gives us a sample of 38 "adaptations to automation" for study. (Recall that different types of analyzers have different performance

characteristics, and that therefore developing an analyzer-compatible version of test method A for a DuPont analyzer is independent of the task of developing an analyzer compatible version of the same method for a Technicon analyzer).

In the numerous instances in which a manufacturer has offered different methods for the performance of a given test on his equipment with the passage of time, the method currently offered on the most recently introduced equipment model was the one we selected for inclusion in the sample. (Technicon's latest model is trade-named the "SMAC High-Speed Computer-Controlled Biochemical Analyzer". The only model DuPont has ever introduced -- and thus its latest model -- is trade-named "ACA -- Automated Clinical Analyzer".) The tests comprising our sample will be found explicitly identified in note a, table 2.

Data collection work for this sample involved literature searches and structured interviews with manufacturer and user personnel. Work on a case would usually begin with a search of the literature for papers related to the test method being examined. Authors whose papers were found germane were contacted and were told that we were interested in exploring the early history of the application of the innovation discussed in their papers to autoanalyzers. We then asked them for the names of fellow-experts with user and/or manufacturer and/or other relationships to the innovation who might have a good knowledge of these matters. Finally, we asked these initial contacts for any knowledge which they themselves might have on the topic of interest. Individuals identified for us by initial contactees were contacted in turn, and the process repeated until we felt we had the information we needed well documented.

During our literature searches, we found two data sources especially useful:

- The MEDLINE computerized index of the medical literature described previously
- "Product labeling" -- U.S. Food and Drug Administration terminology

for methods-relating information which the suppliers of clinical test chemistry methods make available to their customers. We acquired product labeling from both Technicon and DuPont for all methods in our sample. These contained references to publications on chemical test methods used and, in the case of Technicon labeling, also contained references to publication reporting adaption of methods to automation and the results.

### 6.1 Findings

Our goal in this portion of the study was to determine whether user innovation activity could be observed in the development of commonly-used analyzer-compatible test methods offered commercially by Technicon and DuPont. The measure used in table 2 - did a user develop and report on the use of a sampled method on a manufacturers equipment before that manufacturer made it commercially available - was designed to indicate both the appropriateness and the timeliness of this subset of user method development activity. Observe, however, that the measure does not indicate whether analyzer manufacturers exploited the user work or developed essentially the same results independently: It only indicates that the user results were available.

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Insert Table 2 Here

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In table 2 we see the interproduct difference in user innovation activity which we would expect from our table 1 findings, No analyzer compatible test methods in our sample which DuPont offers commercially for use on its aca were developed first by users insofar as we could determine, while 74% of the sampled analyzer-compatible methods which Technicon offers commercially for use on its SMAC model were performed first



Table 2: Adaptations to Automation of Test<sup>(a)</sup> Methods  
Offered Commercially by Equipment Manufacturers

Were First Performed <sup>(b)</sup> By:						
To Users Of:	%user	user <sup>(c)</sup>	Equip. Mfr.	Reagent Mfr.	NA	Total
DuPont ACA	0	0	18	0	0	18
Technicon SMAC (d)	74	14	4	1	1	20

p < .0001 (Fisher exact)

- Notes: (a) As explained in the text, the sources of adaptation to automation of the twenty clinical chemistry tests performed with greatest frequency in 1977 were examined. The identity of these twenty tests: Albumin; Alk Phos; Calcium; Chloride; Cholesterol; CPK; Creatinine; Direct (conjugated) Bilirubin; Glucose; SGOT; SGPT; Inorganic Phos; LDH; Potassium; Sodium; Total Protein; Triglycerides; Urea Nitrogen; Uric Acid. (All 20 are offered by Technicon; DuPont offers all by potassium and sodium).
- (b) The measure used: Did we determine that one or more "users" (see note (c) for definition) published a report of adaptation and clinical use of a given test method on DuPont or Technicon equipment with publication date prior to date of commercial introduction of that method (as reported by equipment manufacturer personnel).
- (c) Those who performed the adaptation to automation of a test method were coded as "users" on the basis of professional affiliation rather than motive for performing the work. (We felt that data on the former would be the more reliable measure when collected retrospectively.) In the event, all except three "users" were found to be professionals working in clinical laboratories of non-profit hospitals. The three exceptions worked in an Automated Methods Lab in a VA Hospital -- affiliated with that hospital's clinical lab but not themselves performing day-to-day lab work.
- (d) The SMAC is the latest of several models of Technicon Analyzers utilizing the principle of "continuous flow analysis" (see text). Some of the methods offered by Technicon to SMAC users were adapted to continuous flow on the SMAC, others were adapted on other models of continuous flow analyzers and found appropriate for use on SMAC as well.

by users ( $p < .0001$ , Fisher exact). We thus speculate that, user method development activity involving automated clinical chemistry analyzers is not exclusively directed to exotica: Users sometimes develop methods of general interest.

#### 7.0 Findings Regarding the Generalizability of Firm Innovation Patterns Seen

In this paper we have carefully examined only one of the categories of innovation which would be of concern to firms wishing to manufacture automated clinical chemistry analyzers - development of test methods adapted for use on automated equipment. In this category we found users more strongly involved in innovation work related to Technicon and Abbott Labs equipment than to DuPont equipment. This does not mean, however, that Technicon and Abbott Labs can assume that users are involved in all categories of its analyzer innovation work or that DuPont can assume the opposite. Indeed, some limited data we have for DuPont and Technicon regarding three other categories of work which would be of interest to automated clinical chemistry analyzer manufacturers suggests strongly that such an assumption would not be warranted;

In our sample of commonly-used clinical test methods appropriate for use on automated equipment, we found that, invariable, the method studied was adapted from pre-existing manual methods. (The work involved in these adaptations ranged from easy to difficult. Where the task was easy, all that might have been involved, for example, was adjustment of the concentrations of the serum sample and/or reagents specified for the manual version of the test so that the test results fall within the linear range of the automated equipment's detection instrumentation. Where the task was difficult, nothing would fit: side reactions which didn't affect the manual performance of the test would badly interfere with the operation of the automatic equipment. Steps taken to solve this problem would also have the unintended effect of reducing test sensitivity to an unacceptable level -- and so on.)

As a rapid check on the source of the manual methods behind the adaptations we examined, we turned to the "package labeling" which, as we noted earlier, we had acquired for each of the method adaptations in our sample. Since, in each instance, this material referenced publications regarding the manual method upon which the adaptation described was based, we were able to quickly retrieve papers by the method developers. When these papers supplied the organizational affiliation of the developers, we recorded it, with the results shown in table 3.

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Insert Table 3 Here

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Note that, for this category of innovation work, both manufacturers equally relied on innovation by members of non-profit institutions. (As we did not contact the authors of these papers, we are unable to report more precisely on the developers' relationship to the method they developed: On the face of it, they could have been either users or research scientists with no interest in the methods' practical applications).

- We briefly examined an additional category of innovation task which must be accomplished if a manufacturer of autoanalyzer equipment wishes to premix and sell the reagents which are required for test methods adapted for his equipment. In essence, this task involves stabilizing the reagents so that they will have shelf life sufficient to survive the time lags expected in the distribution and use cycles. This task can be quite difficult in the instance of certain reagents. We did not study this category on a case-by-case basis, we can report anecdotally that users and manufacturers alike informed us that this task is "almost

Table 3: Source of Manual Chemical Test Methods Adapted  
For Automation of DuPont ACA and Technicon SMAC

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<u>Adaptation of Method</u> <u>Offered by</u>	<u>Affiliation of Method Developer</u>	
	<u>Manufacturer</u> <sup>(a)</sup>	<u>Non-Profit</u> <sup>(b)</sup>
DuPont	2	16
Technicon	2	18

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Notes: (a) Includes any commercial manufacturer of autoanalyzer  
equipment and/or reagents

(b) Includes hospital, university and institute affiliations

Data source: "Package labeling" for twenty most frequently  
requested tests (cf. table 2 for explicit identification of  
tests. Technicon labeling obtained from Technicon Corp.,  
Tarrytown, New York, DuPont labeling obtained from DuPont  
Company, Instrument Products Automatic Clinical Analysis  
Division, Wilmington, Delaware.

always" undertaken by the reagent manufacturer.

- Finally a category of innovation related to automated clinical chemistry analyzers - equipment improvement innovations - does show the same interbrand differences in user innovation activity which we observed in the instance of user development of chemical test methods. Our sample of equipment improvement innovations was generated by first identifying and listing the major equipment changes offered by each manufacturer after bringing their first clinical chemistry analyzers to market. These listings were made with the aid of knowledgeable manufacturer personnel primarily. Next, we discussed these lists with users and manufacturer personnel and arrived at an informal consensus as to which of the commercially introduced improvements had offered a "significant increment in functional utility to the user relative to that provided by the equipment previously commercially available from that manufacturer" (No formal measure of consensus was used). The samples which resulted from this procedure are explicitly identified along with our findings related to them in Table 4. Data collection for this sample involved telephone interviewing of expert user and manufacturer personnel only. While multiple sources were queried regarding each innovation, we did not follow our usual practice in this sample of also validating our data via an independent literature search.

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Insert Table 4 Here

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As table 4 shows, we were able to identify 12 Technicon equipment improvement innovations which met our selection criterion, but only one such innovation in the instance of DuPont: DuPont equipment, we found, has remained almost unchanged since its commercial introduction.<sup>(12)</sup> (We do not mean to suggest via this observation that DuPont is somehow "less innovative" than Technicon. As we will discuss in a later section, each company's pattern of equipment improvement might well be appropriate to its overall commercial strategy.

Table 4: Source of Commercialized Hardware -- Embodied Innovations  
in DuPont and Technicon Autoanalysis Equipment

	First Device Routinely Used in Clinical Lab Developed and Built by: (a)
Dupont Autoanalysis Equipment Innovations:	
First commercialized model	mfr.
Improved computer control	mfr.
Technicon Continuous Flow Autoanalysis Equipment Innovations:	
First commercialized model	user
Major detector improvements	
flourometer	user
flame ionization photometer	mfr.
ion selective electrodes	mfr.
Major flow cell improvements	
smaller volume/adjacent debubbler	user
bubble-gated	mfr. (b)
Major dialysis improvements	
shorter flow path/type C membrane	mfr.
type H membrane	mfr.
Other major improvements	
multiple channel equipment	user
physician-readable chart output	user (c)
Reduction in sample carryover	
reduced tubing diameter	user
air/sample/reagent pump synchroni- zation	mfr.
Multiple bubble introduction by sample probe	mfr.
computer compensation for carry- over	user

notes: (a) Our source coding is based on whether manufacturer or user was first to develop and build a device displaying the operating principles and function of the later-commercialized device. The precise embodiment of the user and manufacturer versions may differ,

however. (Thus, user versions of the "smaller-volume flow cell with adjacent debubbler" were assemblies while the commercial version was near-monolithic).

- (b) A very innovative user, Ralph Thiers, is well known for having contributed to this innovation, but in his view, Technicon produced the first commercializable design in-house, and we concur;
- (c) Developed by Dr. Leonard Skeggs, the same innovative user who developed the first continuous flow autoanalyzer. Although well connected with Technicon at the time of this development, Skeggs was not employed by Technicon. He built the first device "in his basement" and clinically evaluated it in his VA lab before turning it over to Technicon for commercial manufacture.

Technicon might well wish to emphasize equipment sales, and thus have an incentive to introduce equipment improvements which would induce users to "trade up". DuPont, on the other hand, might wish to emphasize sales of its disposable test packs. If so, it would have an incentive not to make equipment changes which would obsolete equipment already in the field, but rather to try and keep up with evolving technology via equipment-compatible changes in the test pack portion of the system).

Note that the single DuPont equipment improvement innovation identified which offered a major increment of functional utility to the user -- an internal computer of greater capability -- had a DuPont source. No user development was involved insofar as we could determine. Although the DuPont equipment innovation sample is unfortunately not large enough to test the hypothesis, we would suggest that it is only logical that all or most such DuPont equipment improvement innovations would come from an in-house source. Automated clinical chemistry analyzers, after all, are designed to perform chemical procedures. If manufacturer-offered equipment is appropriate for the performance of manufacturer-offered chemical procedures; user incentive to change the equipment would be derived from user interest in performing non-standard chemistries on the equipment. And, as we saw in an earlier section, certain design features of the DuPont equipment militate against users turning to it for implementation of non-standard work. Similar logic can be used, we suggest, to explain the observed presence of user-development activity related to our sample of commercialized Technicon equipment improvement innovations. Users, as we have previously seen, do find Technicon equipment suitable for development of non-standard chemical methods. It is therefore logical that they would sometimes have a derived need for related equipment innovations -- and have an incentive to develop these as



well.\*

## 7.0 Relationship of Findings to "Reinvention"

The findings reported in this paper are related to and support the concept of "reinvention" which Rogers et al.<sup>(14)</sup> have developed and empirically examined. Rogers points out that students of diffusions research have tended to regard an innovation as invariant: potential users of the innovation are seen as having only the two choices of (a) adopting the innovation precisely as offered or (b) rejecting the innovation. In the paper cited above, data is provided to show that, in the instance of an information processing tool named GBF/DIME, users often took a third option: their adoption behavior included modification ("reinvention") of the innovation as received so that it would better conform to their needs.

In the work reported on here, we saw Rogers' reinvention ("user innovation" in our terminology) being carried out by some users of one firm's product --

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\* It should be noted that the sample of commercialized equipment improvement innovations identified in table 4 are not the only ones which have been developed over the years. Recall that our sample selection methodology involved asking interviewees to list commercialized hardware improvement innovations. Thus, major improvement innovations developed by users and replicated in limited numbers by members of the user community but never offered commercially by the equipment manufacturer are excluded. The literature shows many such innovations by equipment users such as the adaptation of an Atomic Absorption instrument as a detector on Technicon systems. (13) Such innovations offer Technicon a pool of prototyped and field proven new products which they could offer commercially if they should someday decide there is a market sufficient to make action worthwhile.

but not by users of a similar product supplied by another firm. Thus, we may perhaps contribute to the reinvention concept by suggesting that the relative frequency of reinvention vs. straightforward adoption observed can differ for "equivalent" products, and may be controllable by the manufacturers of some products via product designs which make user reinvention an easy or a difficult task.

## 8.0 Costs and Benefits of

### User Innovation Ability

Our finding that a firm sometimes can influence the level of user product innovation it experiences does not indicate whether a given firm will be interested in doing so. Nor does it suggest whether a manufacturer's interest might lie in the direction of encouraging or discouraging product-related innovation by users and other non-manufacturer personnel. A review of the impact of the level of user method development activities on the strategies and fortunes of Technicon and DuPont in the autoanalyzer field suggests that the considerations which determine a particular firm's stance on these matters can be quite complex, and we now turn to an exploration of this matter.

First, what has Technicon gained from user method development activity? Anecdotal discussions with knowledgeable users and manufacturer personnel suggest the following major categories of benefit:

- increased instrument sales
- free R&D on methods within clinical chemistry
- user involvement in development and proof of value of applications

outside of clinical chemistry. (Approximately 10% or \$20 million of Technicon's 1977 analyzer sales were made to industrial application customers. DuPont aca personnel knew of no instances in which aca was applied to a use other than

clinical chemistry analysis.)

The related costs to Technicon suggested to us:

- costs of screening user innovations and selecting those which they should perform "product engineering" work on and offer for commercial sale.

- inability to capture all sales of reagent used on their machines.

This last is the major cost which may be attributable to the accessibility of Technicon equipment to innovative users, and we will explore it further.

Both Technicon and DuPont manufacture automated clinical chemistry analyzers and reagents appropriate for use in their equipment. Over the years, the commercial importance of reagent sales to both firms has risen relative to that of analyzer equipment sales because: the market for such equipment has begun to approach saturation; more equipment in the field means greater reagent usage. While DuPont has been able to capture 100% of reagent sales to users of its analyzers, Technicon has lost perhaps 30%<sup>(15)</sup> of this market to competing reagent manufacturers. Since Technicon's total reagent sales in 1977 were approximately \$50 million, one can see that this loss -- both direct and in terms of competition-induced reduction -- is monetarily significant. Interestingly, it is likely that the same difference in the design of the two firms' analyzer equipment, discussed earlier as causes of the observed interproduct differences in levels of user method innovation, may also play a role in the observed difference in Technicon and DuPont's success in the capturing of reagent sales. As noted earlier, DuPont's reagents, are sold and used in an elaborate patented package. A would-be competitor must legally contest these patents or "design around" their claims and must invest in expensive tooling for package production if he wishes to produce a substitute compatible with the DuPont analyzer equipment. Technicon's reagents, on the other hand, are supplied to the user in simple bulk containers easily obtainable by anyone.

## 9.0 Summary

The data presented in the preceding pages supports the notion that the level of user product innovation experienced can differ greatly between functionally similar products. In the particular sample we have studied, it appears that the principal cause of the variation in user innovation activity observed appears to lie in the ease with which a would-be-user-innovator can modify a manufacturer's product to suit his particular needs. Doubtless this product design variable has an influence on the level of user innovation experienced by the manufacturers of many types of product in addition to clinical chemistry autoanalyzers: for example, the degree to which a product design allows users convenient access to the software of computerized instruments, word processors, cash registers, etc. might will have an impact on the level of user innovation activity involving that equipment. Note, however, that we do not mean to imply that any easy-to-modify product will induce related user innovation activity. Probably, user interest in modifying a given product is independent of product design: An easy-to-modify product design will simply facilitate the work of interested user-innovators and perhaps determine which of several competing products they will choose to work with. Further note that we do not mean to suggest that product design is the only or usual cause of interproduct variations in the level of user innovation activity. Indeed, we suspect that further research will show that numerous variables controllable at the level of the individual firm can influence that level. Such a prospect complicates the life of the researcher but should please the innovation practitioner - who would gain additional degrees of freedom in management of the innovation process.

Notes and References

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- <sup>7</sup> Peck, M.J., op cit
- <sup>8</sup> Smithson, L.H., Overview of the Clinical Laboratory Market, Pub.: Stanford Research Institute, Menlo Park, California (Date n/a). A very recent publication (S. Solomon, "Metpath's Biggest Test", Fortune, March 27, 1978, p. 115) estimates aggregate 1978 clinical lab gross revenues at \$11 billion.
- <sup>9</sup> IMS America, Semi-Annual Audit of Laboratory Tests, Hospital Labs, January-June, 1977, and July-December 1977, IMS America, Ambler, PA, 19002.
- <sup>10</sup> National Library of Medicine, Medical Subject Headings - Annotated Alphabetical List, 1978, U.S. Department of Commerce, National Technical Information Service, Springfield, MA (reference # PB-270-894).
- <sup>11</sup> Rautela, G.S. and Liedtke, R.J., "Automated Measurement of Total Cholestrol in Serum", Clinical Chemistry, January, 1978, p. 103-114.
- <sup>12</sup> Several equipment changes are listed in B.W. Perry, T.A. Hosty, et al., A Field Evaluation of the DuPont Automatic Clinical Analyzer (published by DuPont, Wilmington, DE [date of publication not given: date of second printing, January 1972]. We did not include these changes in our sample because they were made prior to the commercial introduction of the DuPont aca. If we had included them, they would

not have changed our finding that users do not develop equipment improvement innovations for the aca: while the monograph authors were users at the University of Alabama Medical Center, Birmingham, AL, the equipment problems uncovered by their evaluation work were rectified by changes developed by DuPont personnel.

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